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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,722	08/27/2001	Ronald A. Schachar	PRES06-00217	5803

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EXAMINER

WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/940,722	Applicant(s) SCHACHAR, RONALD A.	
	Examiner Dave Willse	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 61-106 is/are pending in the application.
- 4a) Of the above claim(s) 71-73, 91-93 and 104-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 61-70, 74-90, and 94-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3-31-06</u> . | 6) <input type="checkbox"/> Other: _____ |

The Applicant's election of Species I (Figures 6-8) in the reply filed on April 19, 2004, is acknowledged. Because the Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The disclosure is objected to because of the following informalities: In the amendments to the specification received on February 6, 2004, "platform" should be replaced by --planform-- on line 1 of the paragraph to be substituted at page 16, line 18, of the specification. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 69, 75-77, 89, and 94-102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 69 and 89, lines 1-2 of each, "one of said first dimension" lacks proper syntax. In claim 75, line 1, "said base" lacks a proper antecedent basis. Claim 76 fails to further limit claim 74 because the elongated body being "elongated" (among other *options*) does not narrow the scope of the claim. In claim 77, line 3, "said base" lacks a proper antecedent basis. In claim 94, line 5, "the pocket" lacks a proper antecedent basis. In claim 100, line 1, "said outer surface" lacks a proper antecedent basis; on lines 1-2, "said base" lacks a proper antecedent basis. In claim 101, line 1, "said ridge *member*" (emphasis added) lacks a proper antecedent basis; on line 2, "said first dimension" and "said base member" lack proper antecedent bases. In claim 102, lines 1-2, "one of said first dimension" lacks a proper antecedent basis and lacks proper syntax.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 61-68, 70, 74-88, 90, 94-101, and 103 are rejected under 35 U.S.C. 102(b) as being anticipated by Schachar, US 5,354,331. Regarding claim 1 and others, Schachar '331 discloses an ocular scleral prosthesis in the form of an adjustable scleral expansion band (column 7, lines 1-4) comprising at least one elongated body in the form of a strip of material (column 7, lines 4-8) capable of being implanted in a corresponding elongated pocket within scleral tissue of an eye in the zone exterior to the ciliary body (column 7, lines 36-39). Inner and outer surfaces of said flap are capable of contacting the base and the flap of the scleral pocket (column 7, lines 39-42; drawings) and are separated by enough distance or thickness to impart sufficient structural characteristics (e.g., strength) to elevate the flap and exert outwardly directed traction on at least the anterior margin of the pocket (column 7, lines 8-12; column 5, lines 38-41; etc.). Regarding claim 62, the ridge or crest limitation is met by the thread of the screw mechanism (column 7, lines 8-12), which is a means for expanding the contacted sclera to increase the effective working distance of the ciliary muscle (column 7, lines 8-12; column 2, lines 67-68; etc.). Regarding claim 88, the *helical* ridge or thread extends along *both* dimensions of the strip

planform. Regarding claim 94, the tangential screw mechanism (involving a ridge member or thread) on the base member or strip of material applies a force to the scleral pocket via the strip of material.

Claims 69, 89, and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schachar, US 5,354,331. The particular dimensions for each of the “plurality of parts” (column 7, line 2) would have been obvious from anatomical considerations.

The Applicant’s remarks have been considered. The examiner agrees with the Applicant’s conclusion that the Schachar ‘331 variations relied upon in the above grounds of rejection are in the form of a complete ring. However, the transitional term “comprising” (e.g., current claim 1, line 1) is inclusive or open-ended (MPEP § 2111.03) so that the prosthesis as claimed could include additional elongated bodies or other elements; hence the “elongated body” as claimed need not correspond with the band *in its entirety*. The ends of a strip do not vanish when they are affixed to each other or to ends of other strips; in fact, overlapping ends are relied upon to provide adjustability to the device. The elongation or length of the strip or strips is likewise maintained so as to contribute to the circumference of the scleral expansion band. The Applicant contends that “[t]he tangential screw mechanism adjusts the circumference of the complete band before the complete band is inserted into the eye” (page 21, lines 7-9, of the Applicant’s reply of February 6, 2004; emphasis in original), but such a purported scheme is not even possible for the embodiment described on page 20, last three lines, of said reply. Even if the Applicant is correct and the tangential screw mechanism is to be removed for some reason, the implant would then require some sort of mechanical connector to maintain the band in its adjusted state. Such a connector would then serve as the means for expanding the contacted

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sclera by providing a reaction force to support the overlying tissue (Schachar '331: column 7, line 40) and to prevent a reduction in band circumference. Other issues are adequately addressed in the grounds of rejection presented above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Dave Willse
Primary Examiner
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